

Claim 14. Applicants respectfully assert that Claim 3 is not indefinite as written. The terms "edible polymer", and "land plant extract" are defined in the specification at page 7 line 1, to page 7 line 9. The term "derivatives thereof" means derivatives of the listed ingredients. The term "combinations thereof" means combinations of the listed ingredients. Applicants assert that the meaning of the terms in Claim 3 are clear and well supported in the specification and request that the rejection as to Claim 3 is withdrawn.

Finally, the office action fails to state specific grounds for the rejection of Claim 1 under 35 U.S.C. § 112. During a telephone conference on September 16, 2002, the Examiner stated that Claim 1 was rejected because some of its dependant claims were rejected under § 112. The Examiner stated that the rejection as to Claim 1 would be withdrawn upon the removal the § 112 rejection for dependant Claims 3, 10 and 12. While Applicants respectfully disagree with this reasoning, Applicants assert that the § 112 rejection for Claims 3, 10 and 12 has been overcome and request that the rejection of Claim 1 under § 112 be withdrawn.

In the Office Action, pending Claims 1-14 and 16 have been rejected under 35 U.S.C. §102 in view of U.S. Patent No. 5,948,430 ("*Zerbe*"); U.S. Patent No. 4,777,046 ("*Iwakura*"); and EP Patent No. 0 547 551 ("*Lazard*"). Pending Claim 19 has been rejected under 35 U.S.C. §103 in view of *Zerbe*. Of the pending claims, Claims 1, 14, 16 and 19 are the sole independent claims.

Claim 1 relates to a pullulan free edible film composition; Claim 14 relates to a method of making a pullulan free edible composition; Claim 16 relates to a method of delivering a medicament; and Claim 19 relates to a method of treating halitosis. Each of the independent claims requires, in part, a pullulan free edible film composition comprising a film forming agent comprising carageenan, an effective amount of at least one bulk filler agent, and an effective amount of at least one plasticizing agent.

It is believed that the unique combination of the present invention comprising a film forming agent comprising carageenan, a bulk filler agent, plasticizing agents, and optionally thickening agents produces a "stand alone" edible film composition which exhibits many of the same desirable properties found within more expensive pullulan-based films. It has been discovered that the pullulan free edible film compositions of the present invention exhibit rapid dissolution, non-hygroscopicity, clean mouth feel, clean flavor and ease of manufacture like that of currently available pullulan-based films.

“Under 35 U.S.C. § 102, anticipation requires that each and every element of the claimed invention be disclosed in the prior art ...” *Akzo NV v. U.S. International Trade Commission*, 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). The Court of Appeals for the Federal Circuit has held that “a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a *single* prior art reference.” *Verdegaal Bros v. Union Oil of California*, 814 F.2d 628, 631 (Fed. Cir. 1988) (*emphasis added*). Additionally, “the identical invention must be shown in as complete detail as is contained in the claim.” *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989).

In the Office Action, Claims 1-14 and 16 were rejected under 35 U.S.C. § 102 over *Zerbe*, *Iwakura* or *Lazard*. *Zerbe* discloses a composition containing therapeutic agents and/or breath freshening agents for oral use. The film forming material in *Zerbe* is made from water soluble polymers, preferably cellulose derivatives; one or more polyalcohols, a pharmaceutical ingredient, a cosmetic ingredient, and optional ingredients, including plasticizers, surfactants, color, flavor and sweetener. Significantly, *Zerbe* does not disclose a film forming agent comprising carageenan.

Iwakura discloses a sustained release preparation for oral use comprising a drug, gelatin or agar, gluten, a carboxyvinyl polymer, a polyhydric alcohol, a gum, wax and water. The sustained release preparations of *Iwakura* are designed to remain in the oral cavity for a long time. The film preparation of *Iwakura* absorbs saliva in the oral cavity and swells so that the adhesive strength is increased on its surface thus enabling the film to be kept in the oral cavity for a long time. The claims in the pending case, as amended, disclose a pullulan free edible film comprising carageenan which dissolves rapidly in the mouth. Thus, *Iwakura* does not anticipate the claims of the present invention.

Lazard discloses edible films that provide a transmission barrier to water, lipids, solute, gas, etc. in food and pharmaceutical applications. The film is made from a modified starch, gelatin, plasticizer, water and lipid. The composition may optionally include a polysaccharide such as cellulose. In contrast to the edible films of the present invention, the clear focus of *Lazard* is to provide a film barrier to prevent the transmission of materials in food and pharmaceutical applications. Moreover, *Lazard* does not disclose a film forming agent comprising carageenan which dissolves rapidly in the mouth, as described in the claimed

invention. Thus, the composition disclosed in *Lazard* does not anticipate the claims of the present invention.

Accordingly, Applicants assert that none of the references cited by the Patent Office disclose all of the features of the Applications' invention as amended herein. Significantly, none of the cited references discloses a film forming agent comprising carageenan in combination with other ingredients such as bulk filler agents and plasticizing agents. Therefore, each and every element of the claimed invention is not disclosed by the references as required by § 102. Consequently, the rejections of the Patent Office under § 102 are improper and should be withdrawn.

In the Office Action, Claim 19 is rejected under 35 U.S.C. § 103 as being unpatentable over *Zerbe*. As discussed above, *Zerbe* does not disclose or suggest a film forming agent comprising carageenan. The film forming agents disclosed in *Zerbe* are limited to hydrophilic polymers, preferably, cellulose polymers. Nowhere does *Zerbe* mention the use of carageenan as a film forming agent. The Applicants have found that the unique combination of a film forming agent comprising carageenan, a bulk forming agent, and plasticizing agents produces a "stand alone" edible film composition which exhibits rapid dissolution, non-hygroscopicity, clean mouth feel, clean flavor and ease of manufacturing.

Applicants respectfully submit that *Zerbe* does not teach or suggest Applicants claimed invention and the rejection under § 103 is improper and should be withdrawn.

Applicants submit that in view of this amendment all claims are in condition for allowance. Notice to that effect is respectfully requested.

Accordingly, Applicants respectfully request reconsideration of their patent application and earnestly solicit allowance of the same.

Respectfully submitted,

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Please amend Claims 1, 10, 12, 14, and 15-19 as follows:

1. (Amended) A pullulan free edible film composition comprising:
an effective amount of ~~at least one~~ a film forming agent comprising carageenan;
an effective amount of at least one bulk filler agent; and
an effective amount of at least one plasticizing agent wherein the edible film dissolves
quickly in the mouth of the user.

10. (Amended) The composition of Claim 1, wherein the composition further
~~includes~~comprises an effective amount of at least one medicament.

12. (Amended) The composition of Claim 1, wherein the composition further
~~includes~~comprises an effective amount of at least one additive agent.

14. (Amended) A method of making a pullulan free edible film composition
comprising the steps of:
providing an effective amount of ~~at least one~~ a film forming agent comprising
carageenan; and
adding an effective amount of at least one bulk filler agent and an effective amount of at
least one plasticizing agent with the film forming agent to produce a pullulan free edible film
composition wherein the edible film dissolves quickly in the mouth of the user.

15. (Amended) The method of Claim ~~14~~14, wherein the method further
~~includes~~comprises the step of adding an effective amount of at least one thickening agent to form
the pullulan free edible film composition.

16. (Amended) A method of delivering a medicament comprising the steps of:

providing a pullulan free edible film composition which ~~includes~~comprises an effective amount of at least one medicament in the film composition to an individual, wherein the film composition further comprises:

- an effective amount of ~~at least one~~ a film forming agent comprising carageenan;
- an effective amount of at least one bulk filler agent; and
- an effective amount of at least one plasticizing agent; and

orally consuming the film composition by the individual to release the medicament into the oral cavity wherein the edible film dissolves quickly in the oral cavity of the user.

17. (Amended) The method of Claim ~~20~~16, wherein the medicament is a member selected from the group consisting of a pH control agent, an oral care agent, a breath freshening agent, a pharmaceutical agent, a nutraceutical agent, a salivary stimulant agent, a vitamin, a mineral, derivatives thereof and combinations thereof.

18. (Amended) The method of Claim ~~20~~16, wherein the method further includes the step of incorporating an effective amount of at least one thickening agent into the film composition.

19. (Amended) A method of treating halitosis comprising the steps of:
providing a pullulan free edible film composition which ~~includes~~comprises an effective amount of at least one breath freshening agent to an individual, wherein the film composition further comprises:

- an effective amount of ~~at least one~~ a film forming agent comprising carageenan;
- an effective amount of at least one bulk filler agent; and
- an effective amount of at least one plasticizing agent; and

orally consuming the film composition by the individual to release the breath freshening agent into the oral cavity to treat halitosis wherein the edible film dissolves quickly in the oral cavity of the user.